Statement on Substitution of Generic Antiepileptic Drugs

The Epilepsy Foundation is seriously concerned about mandatory substitution of generic antiepileptic drugs without prior approval of the patient and treating physician. Generic formulations of a number of widely used anti-epileptic drugs are available and present the opportunity to reduce costs. Some states and some institutions (including prepaid health plans) have mandated that the pharmacist fill a prescription with the least expensive available drug.

There may be significant differences between the characteristics of brand name and generic anti-epileptic medications, as well as among generic anti-epileptic drugs. A generic product might be approved as equivalent to a brand name product even if it produces varying bioavailability in some individuals. The FDA guidelines allow for a therapeutic range that is too broad to ensure that each individual will receive the same amount of anti-epileptic drug when switching from a brand name to a generic anti-epileptic drug or from one generic to another.

The fact that these differences may exist could result in adverse effects, including loss of seizure control and the development of toxic side effects. Changing from one formulation of the drug to another can usually be accomplished, and risks minimized, if physicians and patients monitor blood levels, seizures and toxicity.

The Epilepsy Foundation therefore strongly advises that all rule-making bodies -- including those at the Federal and state levels, as well as prepaid medical plans, institutions such as hospitals, correctional facilities, residential facilities and others who make decisions about the availability of certain medications -- address the potential adverse effects of changing from one formulation of an anti-epileptic drug to another, by requiring the prior expressed permission of the treating physician and the patient.

Reporting Problems with Medication Switches

The Foundation maintains that the individual and physician should be notified and give their consent before a switch in medications is made, whether it involves generic substitution for brand name products, or generic to generic substitutions. This is a long-standing

position of the Foundation which has been communicated to the Food and Drug Administration (FDA). The Foundation continues to advocate for policy changes regarding this issue.

The FDA encourages people with epilepsy and physicians to report any breakthrough seizures resulting from switching formulations of a product to the FDA's MedWatch program. For information, call 1-800-FDA-1088 or visit the web site at http://www.fda.gov/medwatch.

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